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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *ET AL.*,
Respondents.

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *ET AL.*,
Respondents.

On Petitions For A Writ of Certiorari To The United States Court Of Appeals For The Fifth Circuit

JOINT MEMORANDUM IN OPPOSITION FOR RESPONDENTS

THE RUBBER MANUFACTURERS ASSOCIATION, INC., *ET AL.*,
AMERICAN PETROLEUM INSTITUTE, *ET AL.*,
CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION,
E. I. DU PONT DE NEMOURS AND COMPANY, AND
THE INDEPENDENT PETROLEUM ASSOCIATION OF AMERICA

(RELATING TO THE DERMAL CONTACT ISSUE)

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January 26, 1979

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THE INDEPENDENT PETROLEUM ASSOCIATION OF AMERICA

(RELATING TO THE DERMAL CONTACT ISSUE)

Respondents The Rubber Manufacturers Association, Inc., and six member companies,[1] the American Petroleum Institute, *et al.*,[2] Chemical Specialties Manufacturers Association, E.I. du Pont de Nemours and Company, and The Independent Petroleum Association of America oppose the issuance of a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit entered in this case on October 5, 1978.[3]

OPINION BELOW

The opinion of the court of appeals is reported at 581 F.2d 493. (App. 1a-33a.)[4] Judge Clark wrote the opinion for a panel of the court comprised of Judges Coleman, Clark and Tjoflat.

[1] The six companies are The Armstrong Rubber Company, The Firestone Tire & Rubber Company, The General Tire & Rubber Company, The B.F. Goodrich Company, The Goodyear Tire & Rubber Company, and Uniroyal, Inc.

[2] The petroleum industry respondents included in the group with the American Petroleum Institute are named in the concurrently-filed companion Joint Memorandum In Opposition, at 2 n.1.

[3] This memorandum focuses on the second question presented for review in No. 78-1036.

See the companion Joint Memorandum in Opposition for respondents' discussion in opposition to issuance of a writ of certiorari based upon the question posed in No. 78-911 and upon the first question presented in No. 78-1036. These similar questions focus upon the airborne exposure limit but bear upon each of the provisions in the benzene standard.

[4] "App." refers to a separately bound Appendix to the Petition in No. 78-911.

JURISDICTION

The judgment of the court of appeals (App. 254a-255a) was entered on October 5, 1978. Petitioner Secretary of Labor has delegated his responsibility for administering the Occupational Safety and Health Act of 1970, 29 U.S.C. § 651 *et seq.* (the "Act"), to the Assistant Secretary of Labor for Occupational Safety and Health ("Occupational Safety and Health Administration" or "OSHA"). The jurisdiction of this court is invoked under 28 U.S.C. § 1254(1).

QUESTION PRESENTED[5]

1. Whether OSHA, in incorporating in the benzene standard a ban on dermal contact with liquids containing even small or trace amounts of benzene, was entitled to rely solely on outdated and inconclusive data while failing to obtain readily available evidence based upon "research, demonstrations, [and] experiments" as required by 29 U.S.C. § 655(b)(5).

STATUTE AND REGULATION INVOLVED

1. The Occupational Safety and Health Act of 1970.

Section 2(b) of the Act, 29 U.S.C. § 651(b), provides in part:

> (b) The Congress declares it to be its purpose and policy, through the exercise of its powers to

[5] As noted *supra* at 2 n.3, OSHA has set forth two questions which it believes are presented by this case, and this response addresses only the second of those questions. Because OSHA's statement of the second question is inadequate, it has been restated.

regulate commerce among the several States and with foreign nations and to provide for the general welfare, to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources . . . .

Section 3(8) of the Act, 29 U.S.C. § 652(8), provides:

> (8) The term "occupational safety and health standard" means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5), provides:

> (5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and the performance desired.

Section 20(a)(1) of the Act, 29 U.S.C. § 669(a)(1), provides in part:

> (a)(1) The Secretary of Health, Education, and Welfare, after consultation with the Secretary [of Labor] and with other appropriate Federal departments or agencies, shall conduct (directly or by grants or contracts) research, experiments, and demonstrations relating to occupational safety and health . . . .

Section 20(c) of the Act, 29 U.S.C. § 669(c), provides:

> (c) The Secretary is authorized to enter into contracts, agreements, or other arrangements with appropriate public agencies or private organizations for the purpose of conducting studies relating to his responsibilities under this Act. In carrying out his responsibilities under this subsection, the Secretary shall cooperate with the Secretary of Health, Education, and Welfare in order to avoid any duplication of efforts under this section.

2. **Permanent Standard for Occupational Exposure to Benzene.** The benzene standard (App. 34a-66a) and the accompanying preambular statement (App. 67a-251a) as originally issued by OSHA are found at 43 *Fed. Reg.* 5917-5970. The amendment to the benzene

standard (App. 252a) and the accompanying preamble[6] were published at 43 *Fed. Reg.* 27,961-27,971.

STATEMENT OF THE CASE

This case presents questions concerning two separate and essentially unrelated provisions of OSHA's Permanent Standard for Occupational Exposure to Benzene (the "benzene standard"). The first of these provisions regulates airborne exposure to benzene and requires employers to assure that no employee is exposed to an airborne concentration of benzene in excess of 1 part benzene per million parts of air (1 ppm) as an 8-hour time-weighted average. The second of the provisions operates independently of the airborne exposure limit and bans dermal contact with benzene or substances containing even small amounts of benzene.[7] (29 C.F.R. § 1910.1028(c)(2); App. at 36a.)

Respondents Rubber Manufacturers Association and six individual rubber companies (collectively "rubber companies"), supported by and joined in this brief by other industry respondents,[8] are affected pri-

[6] The preamble to the amendment has not been reprinted as part of the Appendix to the Petition in No. 78-911.

[7] A related provision of the standard requires employees to wear protective clothing and equipment where dermal or eye contact may occur. 29 C.F.R. § 1910.1028(h); App. at 42a. As described more fully below, the extent of the ban on dermal contact has varied since the issuance of the permanent benzene standard. The standard as originally adopted by OSHA prohibited all dermal contact with any liquid containing any amount of benzene. In the first five months following adoption of the standard, OSHA twice modified the ban on dermal contact.

[8] See *supra* at 2 n.3.

marily by the second of the two major provisions of the benzene standard—the ban on dermal contact. Rubber companies manufacture tires and a range of other products[9] from natural and synthetic rubber. In doing so, they use petroleum solvents, cements and other materials which contain benzene in small or trace amounts (less than 1.0 percent). Rubber company production operations require dermal contact with these solvents, cements and other materials.[10]

The record evidence relating to the dermal contact provisions of the standard is largely independent of the record evidence bearing on the airborne portions. In carrying out its review, the court of appeals made a separate analysis of the record for each of these two key provisions. Accordingly, the statement of the case which follows discusses the procedural posture of OSHA's rulemaking and the record evidence insofar as they relate particularly to the dermal contact issue.[11]

[9] These other products include such diverse items as tubes, hoses, v-belts, conveyor belts, tennis balls, adhesives, cements, tennis shoes, shoe products, and health and hospital products. See, *e.g.*, Comment of Rubber Manufacturers Association (May 12, 1978), Amend. Ex. 46-59, at 3-4. (For an explanation of the form of citation to the original record, see *infra* n. 11.)

[10] *Id.*

[11] The original record has been transferred to this Court from the United States Court of Appeals for the Fifth Circuit. References in this memorandum to the record will be to the original record. Where available, accompanying citations to the Appendix to the Petition in No. 78-911 will also be supplied.

References in this memorandum to the transcript of the hearings held by OSHA in 1977 will be to "Tr." References to the other documentary portions of the rulemaking proceedings on the original standard will follow the form set out in OSHA's certification of the administrative record to the court of appeals.

The statement of the case especially as it concerns the airborne issues is set out in the other joint memorandum being filed concurrently by the same respondents.

A. The Original Benzene Standard

Benzene is a substance to which most of us in the United States are exposed every day. It is found throughout our society, *e.g.*, in ambient air and in minute quantities in water supplies throughout the country.[12] Notably, benzene is present in gasoline, especially unleaded gasoline, at levels ranging up to 2-3 percent. Benzene also is a useful building-block intermediate chemical in its own right. It is present in trace quantities in all petroleum-based products, including essentially all plastics, synthetic fibers, petroleum-based fuels, cleaning fluids, solvents, deter-

Hearings were also held by OSHA in May 1978 on a proposed amendment to the standard. See *infra* at 15-19. References to those subsequent hearings will be to "Amend. Tr." References to the documentary portions of the further administrative record will similarly follow the form used in OSHA's certification of this further record to the court of appeals, except that OSHA's designations will be preceded by "Amend." as in "Amend. Ex. 0-00."

[12] Indeed, OSHA itself found that "Benzene has been detected in foods such as roasted peanuts, soybeans, chicken, meat, codfish, tomatoes, pineapples, strawberries and cheddar cheese." OSHA, Final Environmental Impact Statement on a Standard for Occupational Exposure to Benzene (January 1978), Ex. 223, at 8-9. See also Amend. Tr. 129-130; Testimony of Dr. Herman Kraybill (National Cancer Institute), Ex. 84.B-18, App. A at 2-3, Tr. 1176, 1192-1194; Testimony of Edward Baier (National Institute for Occupational Safety and Health), Ex. 84.A at 7, Tr. 749-750, 1131.

gents, pesticides, and a vast range of other chemical products.

On May 3, 1977, OSHA issued an Emergency Temporary Standard ("ETS") for Occupational Exposure to Benzene. (42 *Fed. Reg.* 22,515.) The ETS exempted from its coverage mixtures containing 1.0 percent benzene or less. Respecting dermal contact, the effect of that exemption was to permit employees to have dermal contact with mixtures containing 1.0 percent benzene or less.[13]

Thereafter on May 27, 1977, OSHA issued a Notice of Proposed Rulemaking for a permanent standard for benzene. (42 *Fed. Reg.* 27,451.) The proposed standard, like the ETS, contained a volume percentage exclusion, exempting from the standard's coverage work operations where "the only exposure to benzene is from liquid mixtures containing 1% (0.1% after one year from the effective date of this standard) or less of benzene by volume, or the vapors released from these liquids." (*Id.* at 27,460.) The preamble to OSHA's proposed permanent standard identified a "major" issue in the rulemaking proceeding to be "whether the final standard should exempt certain specified operations from its coverage." (*Id.* at 27,452.) On this issue OSHA proposed:

> [A] step-down procedure exempting those workplaces in which employee exposure to benzene occurs only from liquids containing benzene of 1% or less with a reduction of that percentage to 0.1% benzene after 1 year. (*Id.* at 27,454.)

[13] As noted in OSHA's Petition at 4, the ETS was challenged in judicial review proceedings, stayed, and never brought into effect.

Comments submitted by the Rubber Manufacturers Association and individual rubber companies protested the proposal to lower the liquid volume exclusion from 1.0 percent to 0.1 percent a year after issuance of the standard. Those comments questioned the availability to rubber companies of solvents containing only 0.1 percent of benzene.[14] The Rubber Manufacturers Association also offered a proposed definition of "liquid benzene" that would have avoided the problems now presented by the dermal contact sections.[15] OSHA's proposed "step-down" procedure underscored its focus upon a percentage exclusion, however, and parties submitting comments on the proposed standard understandably shared that focus. Submitted comments generally assumed that some percentage exclusion, not lower than 0.1 percent, would be adopted in the final regulation.[16]

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[14] B. F. Goodrich Comments (June 27, 1977), Ex - ; Rubber Manufacturers Association Comments (June 27, 1977), Ex. 6-59, at 1, 3; Firestone Comments (June 27, 1977), Ex. 6-48.

[15] Rubber Manufacturers Association Comments (June 27, 1977), Ex. 6-59, at 1, 3.

[16] Statement of Tyler (SOHIO), Tr. at 1815-1818; Rubber Manufacturers Association Comments (June 27, 1977), Ex. 6-59; Firestone Comments (June 27, 1977), Ex. 6-48; Du Pont Comments (June 27, 1977), Ex. 6-46.

The reasonableness of this assumption as to the intended scope of the standard is confirmed by OSHA's own actions during its informal hearings on the rulemaking proposal. For example, OSHA's economic consultant, Arthur D. Little, Inc., was explicitly directed by OSHA to carry out a study of the standard's feasibility on the assumption that the standard would include the 1.0 percent exclusion. Tr. at 507-509. Because OSHA had directed its own consultant to ignore small or trace levels of benzene in mixtures, there was no reason to believe that OSHA was even interested in mixtures containing amounts of benzene below the proposed exclusion level.

During OSHA's informal hearing on the proposed benzene standard, limited evidence was introduced on the dermal contact issue. In proposing the standard, OSHA had candidly admitted that "studies indicate benzene is not readily absorbed through intact skin." (42 *Fed. Reg.* at 27,470.) No significant contrary evidence regarding skin absorption was presented during the rulemaking proceeding. Dr. Howard Maibach,[17] the only witness participating in the rulemaking who reviewed in detail the state of scientific knowledge regarding skin absorption of benzene, concluded that "the overwhelming majority of the observations suggest that benzene does not penetrate the skin."[18] (Tr. at 2465.)

During the rulemaking proceeding, Dr. Maibach repeatedly testified that modern analytic techniques can produce conclusive answers regarding whether benzene is absorbed through skin and the rate of any absorption; whether absorption is affected by multiple exposures; and whether any absorption is harmless or less harmful than inhalation of benzene. (Tr. at 2465-2468.) The necessary tests could have been completed in six to twelve weeks. (Tr. at 2487.)

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[17] Professor of Dermatology, University of California Medical Center.

[18] The single reference in the record suggesting that benzene can be absorbed through the skin was made by Dr. Douglas Smith of the National Institute for Occupational Safety and Health. Without discussing the relevant scientific literature, citing any direct data, or in any other manner suggesting the basis for his opinion, Dr. Smith remarked:

> Apparently it [benzene] is not absorbed through the skin at the same rate as toluene and xylene but it nonetheless can be absorbed. (Tr. at 860.)

Nearly six months after the close of that hearing OSHA published the permanent benzene standard. In contrast to both the ETS and the proposed standard, the permanent standard provided no exclusion whatsoever for mixtures containing trace amounts of benzene. The permanent standard banned all dermal contact with liquid mixtures containing any amount of benzene (29 C.F.R. § 1910.1028(c)(2)),[19] and required employees to wear protective clothing and equipment where dermal exposure might occur (29 C.F.R. § 1910.1028(h)). It also required employers to affix "Cancer Hazard" labels on all containers of all products containing any amount of benzene (29 C.F.R. § 1910.1028(k)).

In announcing the permanent standard, OSHA offered no explanation for its last-minute and unexpected elimination of the exclusion for liquid mixtures with 1.0 percent or less benzene. OSHA imposed the draconian prohibition against dermal contact even though in the preamble announcing the permanent

[19] As noted *supra* at 8 n.12, benzene is present in minute quantities in water supplies throughout the country, as well as in everyday foods and elsewhere throughout our society. Consequently, as initially promulgated OSHA's standard would have produced absurd results. It would have imposed a ban on drinking water in workplaces in the United States and would have required that all workplace drinking fountains bear a "readily visible and legible" label stating: "CAUTION - CONTAINS BENZENE - CANCER HAZARD". 29 C.F.R. § 1910.1028(b), (c)(2), and (k)(2)-(4), as originally issued, 43 *Fed. Reg.* at 5963-5966; App. 34a-48a. See also the opinion of the court of appeals, 581 F.2d at 500; App. 12a. Solid materials would also have been affected. For example, the same label would have been required to be affixed to all cans of tennis balls made in the United States, but not to cans of tennis balls manufactured abroad.

standard, it acknowledged that "[i]nhalation is the primary route of entry of benzene in man." (43 *Fed. Reg.* at 5920; App. 78a.) OSHA further conceded that it did not know whether benzene is absorbed through intact skin:

> The record evidence on the effect of liquid benzene on the eyes or the skin is extremely limited. No scientific data as to the effects of benzene on the eyes was presented during the rulemaking proceeding. The few studies of skin effects on animals and humans are not definitive as to the extent of benzene that is absorbed through the intact skin or as to the comparative rate of absorption through damaged skin. (*Id.* at 5948-5949; App. 193a (citations omitted) .)[20]

Rubber companies filed a request with OSHA for a stay of the dermal contact provisions and certain other sections of the standard.[21] That request focused particularly on the fact that it was not feasible for rubber companies to continue their manufacturing operations in compliance with the ban on dermal contact. Manufacturing operations for tires, tennis balls, v-belts, conveyor belts, hoses and other products nec-

[20] OSHA's Petition incorrectly suggests that OSHA banned dermal contact only with liquids containing more than 0.5 percent benzene. Compare OSHA's Petition at 7 with *id.* at 5 n.4. To the contrary, on the basis of this limited "evidence", OSHA initially imposed a total ban on dermal contact with liquids containing *any* amount of benzene.

[21] Other industry respondents filed motions with OSHA for a stay of the effectiveness of the entire standard.

essarily involve dermal contact with solvents containing small amounts of benzene (less than 1.0 percent).[22]

The manufacture of tires, for example, involves the use of petroleum solvents as tackifying agents essential to the tire building process. (Amend. Tr. 87-89, 160-167, 185-186.) Layers of materials ("plies") swabbed with solvent are manually built up to construct tires. (*Id.*) To achieve the precision of attachment and adhesion critical for tire uniformity and compliance with government standards, full use and dexterity of the workers' hands is required. (*Id.*) Skintight, impervious gloves cannot be used; they would dissolve or become tacky upon contact with petroleum solvents and actually lead to greater hazards and exposure. (Amend. Tr. 78, 89, 133.) Hand creams or "barrier creams" also are not a feasible option to prevent dermal contact with petroleum solvents. (Amend. Tr. 133, 168-169.)

There are no suitable substitutes in tire building and other rubber company operations for petroleum solvents which contain small amounts of benzene as a contaminant. (Amend. Tr. 115-116.) Despite repeated requests by rubber companies, it is not possible to obtain from suppliers solvents which do not contain trace amounts of benzene. (Amend. Tr. 87, 153, 168, 186-187, 208-209, 213.) While the benzene content of such solvents has declined in recent years, it remains well above 0.1 percent and in some instances exceeds 0.7-0.8 percent. (Amend. Tr. 131, 151-153, 175-178,

[22] See Request for Stay on Behalf of Rubber Companies (March 3, 1978), Amend. Ex. 27-III-E-1 and E-2; Rubber Manufacturers Association Comments dated May 12, 1978, Amend. Ex. 46-59, at 3-9; Amend. Tr. 78-82, 87-89, 132-133, 160-167, 212.

196-197.) Very substantial quantities of solvents, exceeding 110 million gallons annually, are purchased by rubber companies throughout the United States from a number of suppliers. Moreover, the benzene content of solvents varies among suppliers, among different plants of the same supplier, and even among different shipments from the same plant of the same supplier. (Amend. Tr. 117-118, 175-178, 200-201, 207-209.)

In response to the various requests for stay, on March 8, 1978 OSHA informed rubber companies and other industry respondents that it would grant a stay of the standard as to "work operations where the sole exposure to benzene is from mixtures containing 0.1 percent or less benzene." (OSHA, Statement of March 8, 1978, ¶2.)

B. The Amendment To The Standard

Thereafter on March 28, 1978, OSHA published a notice of its limited stay of the standard[23] and of a rulemaking proceeding to amend the standard. (43 *Fed. Reg.* 12,890-12,891.)[24] That notice proposed an

[23] The entire benzene standard had previously been stayed by the court of appeals.

[24] OSHA further modified the scope of the standard by means of a "correction" document published March 31, 1978. 43 *Fed. Reg.* 13,561-13,563. Among other changes, OSHA "corrected" the preamble to the standard so as to exclude from the standard solids containing benzene (other than pure solid benzene, which generally exists only in scientific laboratories). One effect of this "correction" was to exclude cans of tennis balls and boxes of tennis shoes from the requirement that they be labeled as a "CANCER HAZARD". See *supra*, at 12 n.19.

amendment to exclude from the standard liquid mixtures containing 0.1 percent or less of benzene. The announcement sought to limit the points at issue to nine specific questions, and interested persons were instructed to address the proposed percentage exclusion only as it related to "airborne concentrations" of benzene. (*Id.* at 12,891.) Notwithstanding OSHA's lack of evidence as to whether dermal contact with liquid mixtures containing small amounts of benzene constituted a health hazard, OSHA sought no evidence on that issue.

Moreover, OSHA refused to consider such evidence in connection with the rulemaking even after the rubber companies expressly warranted to the Agency that Dr. Maibach was conducting a study of issues relating to dermal exposure to benzene. In short, OSHA actually rejected the rubber companies' proffer of such highly relevant, and even crucial, evidence.

During the new rulemaking proceeding, the rubber companies informed OSHA explicitly that Dr. Maibach had been commissioned to conduct the absorption test. (Amend. Tr. 70.) Dr. Maibach's own description of his testing program was received into evidence at the hearing. (Amend. Tr. 71-73.)[25] Nevertheless, Grover Wrenn, OSHA's Director of Health Standards Programs, flatly stated at the hearing that OSHA would not await the results of such a study even though these results could be made available to it within 180 days. (Amend. Tr. 20.)[26] Mr. Wrenn further

[25] Dr. Maibach was unable to appear in person because of his teaching schedule. Amend. Tr. 71.

[26] OSHA's Petition states that "it is surprising that industry parties, with so much money at stake, have not engaged physicians to perform the experiment and furnish the results to the Secretary." OSHA's Petition at 20 n.11. That statement is incorrect. As stated in the text, OSHA was informed of Dr. Maibach's study at the hearing on the proposed amendment to the standard. Moreover, the opinion of the court below specifically refers to Dr. Maibach's study. 581 F.2d at 508 n.27; App. 27a n.27.

Dr. Maibach has now in fact completed his fundamental study of the absorption of benzene with rhesus monkeys. A report of Dr. Maibach's study was submitted by rubber companies to OSHA on January 22, 1979. It is reprinted *infra*, as Appendix 1 to this Joint Memorandum. In important part, Dr. Maibach's study found that only minute amounts of pure benzene or benzene contained in rubber solvents were absorbed through the skin. Dr. Maibach's report states that in a topical application of rubber solvent containing a small amount of benzene, the "actual penetration was 0.0805 ± 0.0119% of the benzene portion (0.36%) of the applied dose, or 0.00029% benzene in relationship to the solvent applied." *Infra* Appendix 1 at 9a.

testified that OSHA did not have any independent plans to obtain data to determine whether a hazard existed from dermal exposure to mixtures containing small amounts of benzene. (Amend. Tr. 18.)[27]

In late afternoon on the day before oral argument in the court of appeals, OSHA announced the amendments to its benzene standard. (581 F.2d at 496 n.4; App. 2a n.4.) OSHA exempted liquid mixtures containing 0.5 percent or less benzene from the provisions of the standard for three years, and thereafter mix-

[27] During the rulemaking proceeding rubber companies strongly urged OSHA to provide in the standard for an "action level" that would permit dermal contact with liquids containing small amounts of benzene, similar in concept to the "action level" now in the standard for airborne exposures to low levels of benzene. Amend. Tr. 67-68, 76, 95, 98-99, 132-134, 136-137, 159, 170, 188-191, 212-215. This suggested solution was similarly ignored by OSHA. See, *e.g.*, Testimony of Mr. Wrenn, Amend. Tr. 62-63.

tures containing 0.1 percent or less benzene.[28] In doing so, OSHA recognized that the dermal contact provisions of the benzene standard posed a "real problem"[29] for rubber companies:

> [W]ith respect to dermal contact, avoidance of skin exposure is feasible for workers in most industrial sectors simply by the use of suitable protective clothing, such as impermeable gloves. *OSHA recognizes that in tire-building, the record evidence shows that at present there are no suitable methods available to prevent skin contact with solvents containing a small amount of benzene.* (43 *Fed. Reg.* at 27,968 (emphasis added).)

OSHA nonetheless chose not to modify the dermal contact provisions, but rather to rely on an across-the-board percentage exclusion providing a modicum of temporary relief for three years.[30] For the longer term, OSHA speculated as to the possibility of increased production of solvents containing less than 0.1 percent benzene and other unspecified technolog-

[28] OSHA also exempted certain previously-packaged mixtures from the standard's labeling provisions.

[29] OSHA's Supplemental Memorandum in Opposition to Stay (April 12, 1978), at 67.

[30] Rubber companies can in most cases obtain solvents at or less than the 0.5 percent level for use in their Eastern, Southern and Midwestern tire and other manufacturing plants. Even for these plants, the companies often are close to or at the 0.5 percent level without any margin for deviation. Amend. Tr. 117, 131, 166-168. For West Coast plants, however, the 0.5 percent level could not be met, since in some instances suppliers could only meet a limit of 0.7 percent benzene in suitable solvents. Amend. Tr. 176.

ical developments, without citing any factual basis and in the face of substantial evidence to the contrary. (43 *Fed. Reg.* at 27,970.) OSHA cited no new health evidence in support of the amendment.

C. Judicial Proceedings And The Decision Below

On March 10, 1978, the American Petroleum Institute, *et al.*, and the Rubber Manufacturers Association, *et al.*, filed motions for stay of the benzene standard with the court of appeals.[31] They were soon joined by other producers and users of benzene who also sought a stay. On March 13, 1978, argument was had before Judge Morgan of the court on the stay motions. Later that day, Judge Morgan issued a temporary stay of the standard pending a hearing before a full panel of the court of appeals.

The issues concerning the stay were then fully briefed by the parties on an expedited basis. Numerous factual affidavits were submitted. A hearing on the stay was had on April 18, 1978 before a three-judge panel of the court of appeals. After the hearing, the court issued an order continuing in effect the temporary stay issued on March 13, 1978, "pending disposition of the petitions for review filed in these cases." In the same order the court of appeals established an expedited schedule for briefing the cases and it provided for accelerated oral argument.

[31] Various parties filed petitions for review of the benzene standard which were considered on a consolidated basis by the court of appeals. 581 F.2d at 4°5 n.1; App. 1a n.1.

Argument to the court of appeals in the consolidated cases was had on June 22, 1978. Since the amendment to the standard had been issued literally on the eve of oral argument, at the close of the argument the court of appeals directed the parties to file supplemental briefs, again on an expedited basis, directed to the effect of OSHA's amendments on the litigation. Thereafter on October 5, 1978, the court of appeals issued its decision granting the petitions for review of the benzene standard, setting aside the airborne permissible exposure limit and the dermal contact provisions, and also vacating the remaining provisions of the standard.

Specifically, the court of appeals vacated the dermal contact provisions on two separate and alternative grounds.[32] Rejecting OSHA's claim that its decision to prohibit dermal contact with liquid mixtures containing small amounts of benzene was supported by "substantial evidence",[33] the court stated that:

> OSHA's decision to regulate on the basis of dated, inconclusive data when modern experimental methods can quickly and efficiently provide reliable information contravenes the directive from Congress to promulgate standards on the basis of the "best available evidence," "research, demonstrations, experiments, and such other information as may be appropriate," and "the latest available scientific data in the field." 29 U.S.C.A. § 655(b)(5). This is not a case where there is testimony that additional research could be attempted, but might not shed new light on a subject. (581 F.2d at 507; App. 26a-27a.)

[32] It did not reach the issue of feasibility of the dermal contact provision, the third asserted ground for setting the provisions aside. See *infra*, at 23.

[33] Petitioner incorrectly asserts that the court of appeals found OSHA's adoption of the dermal contact provisions to be supported by "substantial evidence". OSHA's Petition at 11, 20. To the contrary, the court, after reviewing the "dated, inconclusive data" relied upon by OSHA, stated that "OSHA's finding that dermal contact with benzene poses a cancer risk *could* pass muster" if that had been the only evidence in the record. 581 F.2d at 507; App. 25a (emphasis added). The court then considered Dr. Maibach's testimony describing available and reliable experimental techniques which could resolve within a relatively short

In reaching that conclusion, the court reviewed in detail not only the limited data considered by OSHA but also Dr. Maibach's "unrefuted testimony" as to the reliability and accuracy of straightforward experimental techniques relating to benzene absorption.[34] On the basis of that detailed factual review, the court held that:

> OSHA's choice to rely on old and inconclusive evidence that there is a possibility of absorption

term the issue of whether human skin absorbs benzene, and found that Dr. Maibach's "additional evidence remove[d] the support for OSHA's actions." *Id.*

Indeed, at a prior point in its opinion, where the court summed up its ruling on the dermal contact provisions, the court stated:

> The record therefore fails to support the finding that benzene is absorbed through the skin. Since entry to the body by dermal contact was not established, the record will not support a finding that the prohibition of all dermal contact with benzene . . . [is reasonably necessary]. 581 F.2d at 506; App. 23a-24a.

[34] The court also referred expressly to the fact that the new test results were "so readily available". 581 F.2d at 508; App. 27a.

> of benzene through the skin which might cause cancer is in clear disregard of the Congressional directive as to the kinds of evidence OSHA is required to consider. Therefore, the provision of the standard prohibiting dermal contact with liquid benzene cannot stand on the present record. (581 F.2d at 508; App. 27a.)

The court of appeals also vacated the dermal contact provision on the ground that it was not "reasonably necessary" as required by Section 3(8) of the Act, 29 U.S.C. § 652(8). OSHA had sought in the court of appeals to justify the dermal contact prohibition as an adjunct to the permissible airborne exposure limit and on the basis of a concern for dermatitis. Both contentions were rejected. The court's analysis of the record led it to conclude that the argument on dermatitis "appear[ed] to be a post hoc rationalization for the dermal contact prohibition since it was not a significant part of OSHA's reasoning process that led to [that] provision." (581 F.2d at 505; App. 22a.) Because review of the standard "must be of the reasoning process of the agency at the time it promulgated the standard based on the record before it" (581 F.2d at 506; App. 23a),[35] the court refused to give weight to the newly proffered argument on dermatitis. And

[35] As authority for this principle, the court cited *Dry Color Mfrs.' Ass'n, Inc.* v. *Department of Labor*, 486 F.2d 98, 104 n.8 (3d Cir. 1973), which in turn cites and relies on this Court's decisions in *Citizens To Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 419 (1971); *N.L.R.B.* v. *Metropolitan Life Ins. Co.*, 380 U.S. 438, 443-444 (1965); and *Burlington Truck Lines* v. *United States*, 371 U.S. 156, 168-169 (1962), along with *United States* v. *Allegheny-Ludlum Steel*, 406 U.S. 742, 756-757 (1972).

noting that the record did not support OSHA's finding that benzene is absorbed through the skin, the court determined that:

> [T]he record will not support a finding that the prohibition of all dermal contact with benzene will result in quantifiable benefits in terms of a reduced risk of leukemia justifying the costs of the provision. Thus reasonable necessity is lacking here too. (*Id.*; App. 23a-24a.)

The court of appeals did not reach the issue of whether OSHA's ban on dermal contact was "feasible" within the meaning of Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5), stating that "the amendment to the standard on June 21, 1978, significantly affect[ed] the feasibility issue . . . ." (*Id.*; App. 23a.)

REASONS FOR DENYING THE WRIT

I. The Evidentiary Question Stated By OSHA Is Purely Hypothetical; The Facts And Record Demonstrate That There Is No Evidentiary Issue In This Case Worthy Of This Court's Consideration

The second question OSHA seeks to pose is not presented by the case. As OSHA characterizes the decision of the court of appeals and the record, the court first concluded that the dermal contact provisions of the benzene standard were supported by substantial evidence in the record. (OSHA's Petition at 2, 11, 20.) OSHA then asserts that the court of appeals set aside the dermal contact provisions "because of the possibility that future scientific studies will provide better evidence concerning the need for the

standard." (*Id.* at 2.) Because OSHA's factual premises are not correct, this Court is faced not with the question OSHA would like to present but rather with a very different issue.

The court of appeals actually rejected as insubstantial the "old, inconclusive evidence" which formed the predicate for OSHA's decision to regulate dermal contact as it did. (581 F.2d at 508; App. 27a; see also 581 F.2d at 506; App. 24a.)[36] The court did so in light of *all* the evidence in the record. This included the old data of inconclusive nature and manifest unreliability, plus Dr. Maibach's testimony that a test using radioactive benzene could rapidly and conclusively establish whether, or to what extent, benzene is absorbed through human skin. The court of appeals knew that Dr. Maibach was in fact then carrying forward such a study. (581 F.2d at 508 n.27; App. 27a n.27.)[37] And

[36] Only one study suggested that benzene was absorbed through human skin. The description of that study, set out in the decision of the court of appeals, shows its inconclusive and questionable nature:

> Between 1946 and 1961, experiments were conducted to determine whether human skin absorbed benzene. Although the first several of these studies conducted in the late 1940's and mid-1950's had negative results, one study published in 1961 found that some absorption had occurred and concluded that "the absorption of benzene throughout the skin must not be neglected." The record reveals problems in the interpretation of all of these studies, however. In particular, the 1961 study reporting positive results used a technique compressing benzene-soaked cotton against the skin with a glass plate for prolonged periods, that is recognized today as an efficient way to drive molecules into the skin. 581 F.2d at 506; App. 24a.

[37] During the May 1978 hearings on the proposed amendment to the standard, OSHA had been supplied with the test protocol being used by Dr. Maibach, and the approximate schedule for the study. Amend. Tr. 70-73.

the ruling of the court of appeals was also based on its determination, reflecting the record, that the "factual information [being provided by Dr. Maibach's study] is so readily available." (581 F.2d at 508; App. 27a.)[38]

Given the actual state of the record, which is very far from what OSHA would have this Court believe, the court of appeals reached the eminently sensible result. Moreover, OSHA cannot argue here, as it does respecting the first question presented by its Petition, that the statute bars the Agency from itself being sensible.[39] Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5), directs OSHA in promulgating standards dealing with toxic materials to consider the "best available evidence", to develop standards "based upon research, demonstrations, experiments, and such other information as may be appropriate," and to consider "the latest available scientific data in the field." The decision of the court of appeals faithfully follows and implements these statutory provisions.

Especial note should be taken that the factual representations in OSHA's Petition at 20 and in footnote

[38] The fundamental information, involving absorption tests of radioactive benzene with rhesus monkeys, is now actually in OSHA's hands. See *supra*, at 16 n.26, and *infra* Appendix 1.

[39] As to the first question, pertaining to the "reasonable necessity" for OSHA's standard, OSHA argues that Section 6(b)(5) of the Act "prohibits" the Agency from evaluating cost-benefit considerations or making a risk analysis. OSHA's Petition at 17 n.10. Neither Section 3(8) nor Section 6(b)(5) of the Act impose such a restriction. See the companion Joint Memorandum In Opposition, filed concurrently with this memorandum.

11 (bearing on Dr. Maibach's study) are inexplicable, in light of the record.[40]

This is a record-dependent case, as one would expect, because the second question presented by OSHA's Petition pertains to the evidentiary portions of the standard-setting provisions of the Act. This Court should analyze the record before deciding whether or not to grant OSHA's Petition. Such analysis will show that the question OSHA has stated is not actually presented by the facts. On the facts, Dr. Maibach's test protocol is not a tentative or experimental procedure which possibly could provide evidence bearing on a crucial point. Rather, the experimental methods involving radioactively-tagged benzene are simple, direct and produce conclusive results. They can "so readily" provide, and now actually have provided, fundamental evidence on the absorption point. In the circumstances, this Court should deny the Petition.

II. OSHA's Own Failure To Provide Adequate Notice Of Issues In The Rulemaking Inhibited Orderly Development Of The Record

As described in the statement of the case, *supra*, at 9-10, OSHA failed during the proceedings on the proposed standard to give adequate notice that it was considering covering by the standard any material with any benzene content whatsoever. OSHA's ETS

[40] This Court will have the full record available to it during its consideration of the petitions for a writ of certiorari.

and proposed standard both had a "percentage exclusion", exempting from coverage materials with less than a specified percentage benzene content. (See *supra*, at 9.) When OSHA issued a standard covering any material with any benzene content, its action came as a total surprise, at least to respondents. In the absence of any express notice, it was not reasonable for them or for anybody else to have conceived that even OSHA would establish a benzene standard with the effect, among other things, of banning skin contact with tapwater in workplaces.[41]

Because the rubber companies had relied on the proposed percentage exclusion as limiting their concern with the proposed standard (see *supra*, at 10), they had not then sought to have Dr. Maibach or anyone else carry out a skin-absorption study using radioactive benzene. When the final standard issued without any percentage exclusion, they promptly sought both administrative relief and a judicial stay. (See 581 F.2d at 500 n.19; App. 12a n.19.) They also began work with Dr. Maibach to carry out an absorption study. OSHA subsequently granted a stay as to work operations involving mixtures of 0.1 percent or less benzene, and initiated a rulemaking proceeding to determine whether this or another percentage ex-

[41] As noted, benzene is a widely-occurring, natural organic material. See *supra*, at 8-9. The presence of benzene in potable water supplies in the United States has been reported by, among others, the National Academy of Sciences. And as the court of appeals observed, "the permanent standard prohibited all dermal contact with liquids containing any amount of benzene and it imposed the labeling requirements on all such liquids." 581 F.2d at 500; App. 12a.

clusion should be made a permanent part of the standard. (43 *Fed. Reg.* 12,890-12,891.) It was during these subsequent proceedings on the proposed amendment that the rubber companies presented detailed evidence relating to the infeasibility of tire manufacturing and other operations. As described *supra* at 15-17, in the subsequent proceedings the rubber companies also presented Dr. Maibach's protocol and schedule for his absorption tests using radioactive benzene.

The subsequent proceedings on the amendment accordingly were, and are, very important to the rubber companies. OSHA's decisions on the percentage-exclusion issue provide the impetus for and the emphasis on Dr. Maibach's work. The court of appeals pointedly observed "the major effect of the amendment is on the arguments regarding the feasibility of the dermal contact and labeling provisions." (581 F.2d at 501; App. 12a.) Most importantly here, the development of the factual record in this case can only be explained in light of OSHA's actions on the percentage-exclusion issue. This point was strongly made in the court of appeals, and in reaching its decision the court took cognizance of the problem caused by the lack of notice. (*Id.*)[42]

[42] One of the consequences is that the court of appeals took note of, but did not decide, the claims of the rubber companies that the dermal contact provisions were infeasible notwithstanding the amendment. Thus also, even if this Court were to grant the petition for writ of certiorari as to both questions and render a decision on the merits in OSHA's favor, it would still be necessary to remand the case to the court of appeals for consideration of the rubber companies' feasibility claim.

OSHA's Petition is technically correct in stating that "No one has argued that [OSHA] prevented the parties from performing and submitting such a test [as Dr. Maibach's study]." (OSHA's Petition at 20.) Yet while OSHA did not "prevent" the parties from carrying out an absorption study, neither did it inform the parties that the percentage exclusion would be eliminated from the final standard, and that the ban on dermal contact and thus the question of absorption would be of such concern.[43]

In sum, OSHA's own actions and especially its failure to provide notice to affected parties have inhibited the orderly development of the record. This lack of notice has led directly to the circumstance that the fundamental Maibach study has only recently been completed, approximately eleven months after the original benzene standard was promulgated. More particularly, in part because notice was lacking, the question OSHA would pose to this Court on petition for writ of certiorari is not fairly presented by the facts. The writ should be denied.

On the merits, OSHA should not be allowed to force regulated parties to bear the results of its own derelictions in imposing regulations absent evidentiary support. The court of appeals correctly observed that in the circumstances OSHA itself had to shoulder the responsibility for coming forward with the absorption information:

> When such factual information is so readily available, 29 U.S.C. § *655(b) (5) requires OSHA to ac-*

[43] In its Petition, OSHA almost ignores the fact that a major amendment to its standard was made. *Compare* OSHA's Petition at 7, *with id.* at 5 n.4. It understandably would not care to emphasize the reasons why an amendment was deemed necessary.

quire that information before promulgating regulations which would require an established industry to change long-followed work processes that are not demonstrably unsafe. (581 F.2d at 508; App. 27a (emphasis added).)[44]

III. There Is No Conflict—The Evidentiary Issue Before The Court Of Appeals Was And Is A Matter Of First Impression

OSHA cites no conflict of decisions on the evidentiary issue. To respondents' knowledge there is none. The court of appeals dealt with the matter as one of first impression.

[44] This aspect of the case seems particularly troublesome because OSHA apparently considers that it has power in effect to force parties "to supply [it] with relevant evidence" (OSHA's Petition at 20 n.11), by threatening to act to regulate unless evidence is forthcoming. Respondents do not concede that OSHA has been given such power by Congress in Section 6(b) of the Act, 29 U.S.C. § 655(b).

OSHA itself can obtain technical data if it desires to do so. OSHA may request that the National Institute for Occupational Safety and Health carry out technical studies (see Section 20(a) of the Act, 29 U.S.C. § 669(a)), or OSHA may enter into contracts with private parties to have such studies carried out. See Section 20(c) of the Act, 29 U.S.C. § 669(c).

CONCLUSION

For the foregoing reasons, the petitions for a writ of certiorari should be denied.

Respectfully submitted,

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APPENDIX 1

PERCUTANEOUS PENETRATION OF BENZENE AND BENZENE CONTAINED IN SOLVENTS USED IN THE RUBBER INDUSTRY

by

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January 19, 1979

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APPENDIX H—

H-1: Feldmann, R.J. & Maibach, H.I., "Absorption of Some Organic Compounds Through the Skin in Man", *J. Invest. Derm.* 54:399-404, 1970.

H-2: Wester, R.C. & Maibach, H.I., "Rhesus Monkey as an Animal Model for Percutaneous Absorption", pp. 133-137, in Maibach, H.I. (ed.) *Animal Models in Dermatology*, Churchill Livingstone, Edinburgh, 1975.

H-3: Wester, R.C., Noonan, P.K. & Maibach, H.I., "Frequency of Application on Percutaneous Absorption of Hydrocortisone", *Arch. Dermatol.* 113:620-622, 1977.

H-4: Wester, R.C., Noonan, P.K. & Maibach, H.I., "Variations in Percutaneous Absorption of Testosterone in the Rhesus Monkey Due to Anatomic Site of Application and Frequency of Application", Draft Publication in Preparation.

I. INTRODUCTION

This report describes skin absorption of: 1) full strength benzene; and 2) benzene which is present in trace amounts in solvents used in the the rubber manufacturing industry. The purpose of the study was to determine the extent of benzene percutaneous penetration (if any) using full strength benzene and rubber solvent containing small amounts of benzene. The study was conducted as described in the detailed protocol (Appendix A).*

II. PROTOCOL

Purpose

To determine the extent of benzene percutaneous penetration (if any) and the kinetics thereof.

Method

The experimental details are those described by Feldmann, R.J. & Maibach, H.I., as published in "Absorption of Some Organic Compounds Through the Skin in Man", *J. Invest. Derm.* 54:399-404, 1970 (Appendix H-1).

Parenteral

C^{14} benzene will be injected parenterally into the rhesus monkey, at a dose less than 1 mg. Urine and feces will be collected for appropriate assay of C^{14} to ascertain the completeness of excretion (and the kinetics thereof). Should this demonstrate that benzene (and its metabolites) are largely excreted and not stored, the cutaneous experiments will be started.

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* Funding for the study was provided by certain member companies of the Rubber Manufacturers Association.

Cutaneous

C^{14} benzene will be applied to the forearm of the rhesus and urine and feces collected. The specimens are handled in a metabolic fashion with aliquots examined at least daily for kinetic analysis. The initial skin dose will be approximately 4 micrograms/cm^2.

Solvent

Similar experiments will be performed with the benzene content at a level believed comparable to that found in typical rubber solvents. In this instance the dose calculations include that of the solvent and benzene.

General

1. Animals are already trained to sit in metabolic chairs.
2. Animals are tended to several times daily by staff.
3. All radioactivity counting methods have been extensively used for similar experiments in man.
4. Computer programs for handling the data are operational.
5. Three animals will be utilized in each experiment.

III. RESULTS

A. Parenteral Administration of Benzene

Purpose

To determine the excretion of a parenteral dose of (C-14) benzene. This will be used in percutaneous penetration experiments, as a parenteral recovery control.

Procedure

The dose was given to three rhesus monkeys restrained in metabolic chairs in a carefully controlled environmental

room. The dose given was 0.785 microcuries dissolved in propylene glycol. The dose was injected in the thigh of the monkeys.

Urine samples were pooled at 4, 8, 12 and 24 hours, and then at 24-hour intervals for the remaining four days. Two mililiter aliquots of the urine samples were dissolved in triton-toluene-PPO cocktail and counted. The efficiency was determined using a (C-14) toluene internal standard of 1×10^6 dpm. Additional details are in the detailed protocol attached as Appendix A.

Results

The average excretion was 41.02 ± 9.41% of the injected dose with individual values of 47.04, 45.84 and 30.18%. The last value of 30.18% should be considered only approximate because of the loss of some of the urine in the first sample. The true excretion is most probably in the area of 46% of the injected dose. Analytical data reflecting these results is set forth in Appendix B. This parenteral excretion data is to be utilized in preparing the correction figure for topical experiments, i.e., to correct for incomplete urinary excretion. No significant counts were found in the feces.

B. Percutaneous Pentration of Benzene: Topical Exposure

Purpose

To determine the percutaneous penetration of benzene after a small quantity was placed on the skin and allowed to evaporate.

Procedure

Three healthy rhesus monkeys were isolated in metabolic chairs with a device to isolate one forearm. The monkeys were sedated with Ketamine[R] during the procedure, and their forearm hair was removed with a clipper.

The monkeys were transferred outside the building to minimize inhalation and to preserve the controlled atmosphere of the laboratory. Fifty microliters (43.95 mg) of benzene with an activity of 4.33 microcuries was applied to a 1 inch by 2 inch (12.9 cm^2) area and allowed to dry. The treated arm was kept isolated for four hours.

Urine samples were pooled at 6, 12 and 24 hours and then daily for the remainder of the experiment. The feces were removed and discarded daily. The urine was analyzed by direct scintillation counting in triton-toluene-PPO, and an internal standard was added for an efficiency determination of each sample.

Results

Based upon initial analyses, the amount of label recovered was 0.101, 0.051 and 0.113% of the applied dose with an average of 0.088 ± 0.033% in 120 hours. The excretion of a parenteral dose was 41.0% and using this correction factor the actual penetration would be 0.2153 ± 0.0805%. Data is set forth in Appendix C.

However, the urine's radioactivity was measured by direct counting in triton-toluene-PPO cocktail; this method has an inherent drawback impairing accuracy when the counts in a sample are close to background levels. The potassium concentration in the urine varies, and the potassium has a significant number of *beta* emitting isotopes.

A reanalysis was therefore performed using the chromic acid oxidation method. The samples were oxidized using chromic acid, and the $^{14}CO_2$ evolved was captured and counted by liquid scintillation. This is a more accurate method.

The excretion determined by this analysis are 0.0436%, 0.0500% and 0.118% of the applied benzene dose with an average of 0.0705% ± 0.0412%. Using the correction factor of 2.44 determined in the parenteral study of benzene, the actual penetration was 0.172 ± 0.100%. Data is set forth in Appendix D.

C. Percutaneous Penetration of Benzene: From a Rubber Solvent

Purpose

To determine the percutaneous penetration of carbon 14 benzene as a component of a rubber solvent containing 0.36% benzene. This solvent was supplied by the Rubber Manufacturers Association and its characteristics are described in Appendix E.

Procedure

Three rhesus monkeys were placed in metabolic chairs, and had their forearms shaved three days prior to the penetration experiment. A solvent mixture of the rubber solvent with 0.36% benzene containing 18.7 microcuries per 50 microliter dose was prepared. The 50 microliter dose was applied over an area of 2 in^2 (2 × 1 in.) and allowed to evaporate.

To prevent inhalation of the C-14 benzene the monkeys wore gas masks during the application and evaporation period. The application was done in the open air to preserve the controlled atmosphere of the facility they were housed in.

Urine was collected at 4, 8, 12 and 24 hours on the first day and than 24-hour intervals to 120 hours. The feces were removed and discarded daily.

The urine was analyzed using the wet ashing method; chromic acid was used to oxidize the organic components

in a five mililiter aliquot of urine and the $^{14}CO_2$ was captured in an organic base. The $^{14}CO_2$ was counted via scintillation counting in a toluene-PPO cocktail.

Results

The ^{14}C-benzene and metabolites detected in the urine were at 0.0274%, and 0.036% and 0.0353% of the applied dose with an average of 0.0330 ± 0.0049%. Using the parenteral correction factor of 2.44 the actual penetration was 0.0805 ± 0.0119% of the benzene portion (0.36%) of the applied dose, or 0.00029% benzene in relationship to the solvent applied. Data is set forth in Appendix F.

IV. CONCLUSIONS

Full strength C-14 benzene was injected into rhesus monkeys and its presence was identified quantitatively and kinetically through analysis of the urine and the feces (see section III-A). Radioactive benzene was applied to the forearm of the monkeys to quantitate absorption. Using the correction factor of 2.44 determined in the parenteral study, the actual penetration was 0.172 ± 0.100% of the 100% benzene administered (see section III-B). Carbon-14 benzene as a component of a rubber solvent containing 0.36% benzene was applied topically to the forearm of the monkeys. Using the parenteral correction factor of 2.44, the actual penetration was 0.0805 ± 0.0119% of the benzene portion (0.36%) of the applied dose, or 0.00029% benzene in relationship to the solvent applied (see section III-C). The 0.172% and 0.0805% penetration figures suggest that when similar amounts of benzene are presented in diluted and concentrated forms, proportionally less benzene may be absorbed in the diluted form.

The rhesus monkey was selected for these experiments because it has been shown to be a reasonable model for percutaneous absorption where relevance to man is

sought.[1] While percutaneous penetration is a complex process, it appears from data derived from research with compounds other than benzene that absorption in the rhesus monkey bears a marked similarity to absorption in man.

The above relates to single exposures. In accordance with my earlier understanding with the rubber companies sponsoring this project, we will proceed with experiments to determine the effect on percutaneous penetration of multi-dose exposures to benzene or to rubber solvents containing small amounts of benzene. We do not know whether these experiments will show increased penetration, as previous studies indicate that percutaneous penetration is not necessarily increased by multiple exposures.[2]

Further experiments are necessary in order to draw conclusions as to the comparative amount of benzene absorbed through the respiratory and dermal routes in the rubber manufacturing industry. However, this study makes possible a preliminary judgment as to comparative absorption in humans based upon certain assumptions stated below.

The maximum permissible airborne exposure for benzene in the permanent benzene standard of the Occupational Safety and Health Administration is 1 part per million (ppm). A computation provided by the Rubber Manufacturers Association (Appendix G) indicates a maximum permitted exposure of 28.8 mg benzene over an eight-hour period for a worker doing moderately heavy work.

[1] Wester, R.C. & Maibach, H.I., "Rhesus Monkey as an Animal Model for Percutaneous Absorption", pp. 133-137, in Maibach, H.I. (ed.) *Animal Models in Dermatology*, Churchill Livingstone, Edinburgh, 1975 (Appendix H-2).

[2] Wester, R.C., Noonan, P.K. & Maibach, H.I., "Frequency of Application on Percutaneous Absorption of Hydrocortisone", *Arch. Dermatol.* 113:620-622, 1977 (Appendix H-3); Wester, R.C., Noonan, P.K. & Maibach, H.I., "Variations in Percutaneous Absorption of Testosterone in the Rhesus Monkey Due to Anatomic Site of Application and Frequency of Application", Draft Publication in Preparation (Appendix H-4).

The third phase of the study described in this report involved a single topical application of rubber solvent containing 0.36% benzene to the forearm of the rhesus monkey. The actual penetration was 0.0805 ± 0.0119% of the benzene portion (0.36%) of the applied dose, or 0.00029% benzene in relationship to the solvent applied. To make a preliminary judgment as to comparative absorption of benzene in man, it is necessary to assume that penetration through the portions of the hand exposed to rubber solvent containing 0.36% benzene is the same as penetration through the forearm of the monkey, that percutaneous penetration of the benzene in rubber solvent is not substantially increased by multiple exposures and that the extent of dermal contact does not exceed the equivalent of full palmar contact. If these assumptions are correct, a preliminary judgment is that the amount of benzene absorbed percutaneously from contact with rubber solvent containing 0.36% benzene is a small fraction of the amount of benzene permitted to be inhaled at 1 ppm. Further studies to document or disprove these assumptions are planned.

[The appendices to this report (appendices A-H) are not reproduced here. Those appendices are included in a copy of the report on file with the Clerk.]